



UTILITY APPLICATION

OF

**MICHAEL D. GRIFFIN and
RODOLFO GABA**

FOR

UNITED STATES PATENT

ON

SAFETY SCALPEL

Docket Number: 03-12896

Sheets of Drawings: FIVE (5)

Sheets of Written Description: TWENTY ONE (21)

Express Mail Label

Attorneys
CISLO & THOMAS LLP
233 Wilshire Boulevard, Suite 900
Santa Monica, California 90401-1211
Tel: (310) 451-0647
Fax: (310) 394-4477
Customer No.: 25,189
www.cislo.com

SAFETY SCALPEL

BACKGROUND

Surgical scalpels may have a sturdy handle and a blade portion removably mounted on the handle for use during a given procedure. After the blade has been used, the blade may be removed and discarded, after which the handle may be sterilized and made ready for further use by mounting a new blade. New blades may be packaged in individual sterile packages formed by two sheets of paper or aluminum foil sealing the blade between them, much like finger bandages are packed.

When the blade is to be mounted on the handle, one paper or aluminum foil layer is folded back to expose the rearward or mounting portion of the blade. The package is then grasped so as to press the sides of the blade between the thumb and forefinger while the handle is inserted into the opening of the blade. While the blade should be held so that the cutting edge points away from the user, the potential for injury still exists.

Slipping of the blade within the paper or aluminum foil, in conjunction with the force required to properly install the blade on the handle, may push the blade through the cover and cause injury. Nothing prevents the blade from moving relative to its envelope and nothing prevents the blade from puncturing the cover. Therefore, individuals are subject to injury while installing the blade on the handle.

Upon completion of the surgical procedure, the blade may be either manually detached from the handle and placed in a sharps bin, or the handle with the blade may be inserted into a container, which may break off the blade.

It can be seen that attachment of the blade to the handle may be a hazardous procedure and can easily result in a sharps injury. If the blade is manually detached, a sharps injury can also result, which may be even more hazardous as the blade may be contaminated.

5 During surgical use, the scalpels can accidentally cut the surgeon's fingers, or the fingers of nurses and other support personnel. Furthermore, operating personnel may be accidentally cut when the scalpel is passed between personnel. Blades may need to be quickly removed from the handle during surgery. This may increase the likelihood of injury to either the surgeon or others.

10 Surgeons may have a personal preference as to a particular scalpel handle. The surgeon may prefer a certain weight and feel of a handle for achieving desired results in surgery. Furthermore, some safety systems allow for only a certain handle and certain blade systems to be utilized together.

15 What is needed is a safety scalpel system that would allow for specifically weighted, reusable handles to be used with safety and/or normal scalpel blades.

SUMMARY

Presented herein are various embodiments of a safety scalpel. According to one embodiment is a safety scalpel system including handle capable of coupling to a blade 20 with or without a safety housing.

In another embodiment, a safety scalpel system, including a blade, a handle configured to couple to the blade, and a housing configured to couple to, and to enclose the blade, and to couple to the handle, and allow the blade to selectively couple to the

handle and to selectively decouple from the housing, wherein the handle is configured to couple to the blade with or without the housing.

Another embodiment may include a safety blade housing system, including retaining members configured to couple to a blade, an actuatable tab, a guide member integral with the tab configured to, when the tab is actuated, allow the housing to couple to a handle, and a blade actuator configured to, when actuated, decouple the blade from the handle, wherein the blade couples to the handle when the housing moves between a safe position, and an exposed position wherein the blade is exposed for use.

10 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a safety scalpel system, according to an exemplary embodiment.

Figure 2 is a perspective view of a safety scalpel system, showing the blade housing, according to an exemplary embodiment.

Figure 3 is an elevational view of a safety scalpel system, showing the blade housing and a handle, according to an exemplary embodiment.

Figure 4 is an elevational view of a safety scalpel system, showing the blade housing in a safe position, according to an exemplary embodiment.

Figure 4A is a cross-section view of the blade housing along line 4A-4A from Figure 4, according to an exemplary embodiment.

Figure 5 is an elevational view of a safety scalpel system, showing the blade housing in an exposed position with respect to a handle, according to an exemplary embodiment.

Figure 6 is an elevational view of a safety scalpel system, showing the blade housing engaging a handle, according to an exemplary embodiment.

Figure 7 is an elevational view of a safety scalpel system, showing the blade housing engaging a handle, according to an exemplary embodiment.

5 Figure 8 is an elevational view of a safety scalpel system, showing the blade housing disengaging a handle, according to an exemplary embodiment.

Figure 9 is an elevational view of a safety scalpel system, showing the blade housing apart from a handle, according to an exemplary embodiment.

10 Figure 10 is a perspective view of a handle and blade, according to an exemplary embodiment.

Figure 11 is a perspective view of a handle and blade, according to an exemplary embodiment.

Figure 12 is a top cross-sectional view of a blade housing and handle along line 12-12 from Figure 8, according to an exemplary embodiment.

15 Figure 13 is a top cross-sectional view of a blade housing disengaging a handle, according to an exemplary embodiment.

DETAILED DESCRIPTION

The detailed description set forth below in connection with the appended drawings is intended as a description of exemplary embodiments and is not intended to represent the only forms in which the embodiments may be constructed and/or utilized. The description sets forth the functions and the sequence of steps for constructing and operating the illustrated embodiments. However, it is to be understood that the same or

equivalent functions and sequences may be accomplished by different embodiments that are also intended to be encompassed within the spirit and scope of this disclosure.

A safety scalpel system according to an exemplary embodiment is shown in Figure 1, generally at **10**. System **10** may include a handle **20** and a housing **40**. The housing **40** is configured to house a blade and to couple to handle **20** such that the blade may couple to the handle and housing **40** may slide up handle **20** to expose the blade for use.

Handle **20** may include a grasping structure **22**, which may be configured to be utilized by a user to hold the system when in use. Handle **20** may also include a housing receiving portion **24**, which may be adjacent to, and coupled to, grasping structure **20**. Furthermore, handle **20** may include a blade receiving portion **26** which may be adjacent to housing receiving portion **24**. Blade receiving portion **26** may be configured to couple to a blade with or without housing **40**. In this manner, the handle may be utilized with a bare scalpel blade, or it may be utilized with a blade within housing **40**.

Handle **20** may be tapered, as shown or may have different configurations, including a uniform thickness, as desired by the preferences of the user. Furthermore, it may have other configurations to make it more comfortable to use and may be configured differently for each individual user.

Housing **40** may be configured to slide onto handle **20** in a safe position as the blade **12** may couple to blade receiving portion **26** while the housing **40** encloses the blade **12**, as shown in Figure 4. Blade receiving portion **26** may have a groove **30** that

may be configured to fit into an orifice of a blade 12, and secure to the blade 12 such that a user may utilize the handle 20 and blade 12 as a scalpel. Housing receiving portion 24 may include a top channel 32 and a bottom channel 34 that may be configured to couple to, and receive portions of housing 40. This configuration may make the system more stable, as well as provide structure for coupling the housing 40 to the handle 20.

Housing 40 may include an actuatable tab 42 and a blade actuator 46. Tab 42 may be engagedly couple to a guide member 44 to allow housing 40 to move from a safe position, as shown in Figure 4, to an exposed position as shown in Figure 5. The exposed position may be where housing 40 is adjacent housing receiving portion 24 and a blade is coupled to blade receiving portion 26 and exposed for use.

Tab 42 may be located on the top of housing 40, but may be located in other locations about housing 40 depending on the configuration, as desired. It will be appreciated that other means for allowing housing 40 to move may be utilized, as desired.

Housing 40 may also include stabilizing members 48 which may be configured to couple to top channel 32 and bottom channel 34 to ensure a proper coupling of housing 40 to handle 20, and to stabilize the entire system for use.

Figure 2 shows a system 10, according to an exemplary embodiment, with housing 40 shown exploded. Housing 40 may include inner surfaces and outer surfaces. Housing 40 may further include one or more retaining members 50 that are configured to couple to and retain a blade 12 within housing. As shown, there are three

retaining members, generally on the inner surfaces of housing 40. As shown there may be two retaining members 50, which may be configured to contact the non-cutting end of the blade 12, and one retaining member, which may be configured to enter the orifice 14 of blade 12. It will be appreciated that other shapes and configurations may be utilized for retaining members 50, as desired.

In this view, the interior portion of blade actuator 46 is shown in further detail. With this configuration, a blade 12 may be coupled to housing 40 by retaining members 50 and may be configured to slide onto blade receiving portion 26 and groove 30 to couple to handle 20. When it is desired that the blade be removed, blade actuator 46 may be actuated to bias blade 12 away from handle 20, and to recouple to retaining members 50 and housing 40.

Blade receiving portion 26 of handle 20 may further include a stop 28, which may be configured to contact the end of blade 12, such that blade 12 will securely fasten to handle when it is coupled to handle 20. This configuration may make the system more stable for use.

Figure 3 shows an elevational view of a system 10, again which may include handle 20, housing 40, and blade 12 (hidden). Blade 12 is retained in housing 40, and coupled to retaining members 50. As shown by the directional arrow, housing 40 may be moved toward handle 20, which again includes a blade receiving portion 26. In various embodiments, housing 40 may also include a tab 42 and a guide member 44 which may be coupled to and/or integral with tab 42.

Figure 4 shows housing 40 in the safe position, in which blade 12 is substantially, or completely enclosed by housing 40. Housing 40 may slide onto, or couple to, handle 20 and may remain in the safe position until tab 42 is actuated, and housing 40 is moved toward grasping structure 22 of handle 20. When housing 40 is in the safe position, it may completely enclose blade 12, except for an opening in the front of housing 40, to allow blade 12 to extend outwardly when housing 40 is in an exposed position. When tab 42 is actuated, guide member 44 may be actuated downwardly and couple to top channel 32, such that it will slide within top channel 32, and allow housing 40 to move further toward grasping structure 22, as shown by the directional arrow.

As blade 12 is moved along channel 32, the blade receiving portion 26 may engage orifice 14 of blade 12. Also, when housing 40 is moved toward grasping structure 22, blade 12 may couple to blade receiving portion 26 and remain fixed with respect to handle 20

Figure 4A shows a cross sectional view along line 4A-4A of Figure 4. As shown, stabilizing members 48 may be configured to slide in, to couple to, top channel 32 and bottom channel 34 to allow housing 40 to slide onto handle 20.

Figure 5 shows housing 40 in the exposed position where blade 12 is exposed for use by the user, and housing 40 is not covering blade 12 to allow the user to use the blade 12. As shown by the directional arrows, when housing 40 is to be moved from the exposed position to the safe position, tab 42 may be again actuated which may allow

guide member 44 to reenter top channel 32 to allow housing 40 to move with respect to handle 20.

Figure 6 again shows housing 40 in the safe position, enclosing blade 12. It will be appreciated that as shown by the directional arrows, tab 42 may be actuated again to permit guide member 44 to enter top channel 32 and to allow housing 40 to be returned to the exposed position to allow re-use of the blade and housing, as shown in Figure 7.

Figure 7 again shows the housing 40 in the exposed position, and again the directional arrows show the downward actuation of tab 42 which allows guide member 44 to enter top channel such that the housing 40 may be moved again to the safe position, as shown in Figure 8.

Figure 8 shows the housing 40 in the safe position. In this position, blade 12 may remain coupled to handle 20 via blade receiving portion 26 and groove 30 (not shown). Blade actuator 46 may then be actuated to disengage blade 12 from handle 20 and back to retaining members 50 (not shown), when housing 40 is moved in the direction of the directional arrow. Blade actuator 46 may contact blade 12 and bias blade 12 away from handle 12 and toward housing 40. In this manner blade 12 may selectively decouple and/or re-couple to and from housing 40 and handle 20 such that it may be removed safely and a new or different blade and/or housing and blade system may be utilized, as desired.

Figure 9 again shows the housing 40 and the handle 20 separated after use such that the housing and blade may be safely removed and properly disposed of.

Figure 10 shows a handle **20** and a blade **12** according to an exemplary embodiment. Blade **12** may include an orifice **14**, as shown. Furthermore, handle again may include a blade receiving portion **26** which may include a groove **30**. Groove **30** may be configured to couple to blade **12** and orifice **14** such that the blade **12** will slide onto groove **30** and encounter stop **28** as shown in Figure 11. In this manner, **5** bare blades may couple to handle **20** via this configuration. Furthermore, this maybe generally the manner in which blade **12** couples to handle **20** when substantially being enclosed in housing **40** (not shown) when used within the system. Furthermore, handle **20** may be configured to receive bare blades and/or blades within safety housing **40**. **10** Yet further, handle **20** may be configured with weighting characteristics particular to each individual user, such that many may be made, and the user may be more comfortable with the weight and “feel” of handle **20**.

Blade **12** may also be integral with handle **20**, and housing **40** may move from a **15** safe to an exposed condition. With this configuration the entire system may be disposable. Furthermore, blade **12** may also be made of plastic, and may be formed at, or near the same time as handle **20**.

Handle **20** may be made from polymers, plastics, metals, rubber, and **20** combinations thereof as desired. Blade **12** may be a typical scalpel blade such that it may be used alone with handle **20** and/or with the safety housing system **40**. Blade **12** is typically a common scalpel blade. Many different types and styles of blades may be utilized with the handle **20** and the system **10**. Housing **40** may be made in two parts as shown in Figure 2, however other configurations may be utilized as desired, including

made as a single injection molded piece. Housing may be made from plastics, polymers, rubber, metal, and combinations thereof, as desired.

Figure 12 shows a cross-sectional view of system **10** along lines **12-12** from Figure 8. As shown, when blade actuator **46** is actuated downwardly as depicted by the directional arrow labeled **A**, it may contact blade **12** and disengage blade **12** from blade receiving portion **26** of handle **20** as housing **40** is moved in the direction of the directional arrow labeled **B**. Furthermore, when housing **40** is moved in the direction of the directional arrow **B**, away from handle **20**, blade will stay generally stationary with respect to housing **40** and may contact, and be coupled to, retaining members **50**.
In this manner, blade **12** may decouple from blade receiving portion **26** of handle **20** and selectively recouple to housing **40**.

As shown in Figure 13, handle **20** is removed from housing **40** while blade **12** stays generally stationary with respect to housing **40** and recouples to housing **40** via retaining members **50**. Furthermore, blade actuator **46** returns to a steady state position as shown in Figure 13. With this configuration, blades may easily selectively decouple from handle **20** and recouple to housing **40** such that the blade will not be exposed, which may increase the safety of users. Furthermore, housing and blade may then be disposed of, and/or put into a container to be counted later.

Housing **40** may selectively attach, detach, and reattach to handle **40**, as desired. This configuration would allow a user to reuse a blade and housing, as needed.

It will be appreciated that many of the housing **40** and blade systems may be utilized and/or reutilized during one operation as the blades **12** become dull and/or if different blades are needed for different tasks. Furthermore, handles **20** may be utilized with or without a housing **40** and with a blade **12** separately such that in emergency situations a typical scalpel blade may be utilized without the housing **40** and blade system. Furthermore, handles **20** may be weighted, configured and/or designed to the particular preferences of the surgeon such that surgeons may be more likely to utilize them. Additionally, many handles **20** may be made to the specifications of a user, such that they may be thrown away and/or reused, as desired. With this configuration, handles may be more likely to be used by surgeons as they may conform to the surgeons' particular wants and needs as far as stiffness, weight, and other characteristics of a handle, among others.

In closing, it is to be understood that the exemplary embodiments described herein are illustrative of the principles of exemplary embodiments. Other modifications that may be employed are within the scope of this disclosure. Thus, by way of example, but not of limitation, alternative configurations may be utilized in accordance with the teachings herein. Accordingly, the drawings and description are illustrative and not meant to be a limitation thereof.